University of Pennsylvania

Important Information about COVID-19 and In-Person Research Participation

The “you” referenced in this information sheet either refers to the participant, “your child”, or the individual you are providing consent on behalf of as a legal authorized representative, as applicable.

You are receiving this information sheet because you will be having in-person visits with researchers which may increase your risk of being exposed to and spreading SARS-COV-2, the virus that causes COVID-19 disease. This is being provided to you in addition to the information provided during your original consent process. Your participation continues to be voluntary. You may choose not to participate or may withdraw your consent to participate at any time, and for any reason, without jeopardizing your future care at this institution or your relationship with this institution.

Coronavirus disease 2019 (COVID-19) is a new illness caused by a novel (previously unidentified) coronavirus (SARS-COV-2). Vaccination is the primary strategy used to prevent the spread of the virus. Physical distancing, wearing a face mask, and hand-washing are also used to prevent the spread of the virus. Research personnel will follow any applicable and current federal, state, and local recommended steps designed to minimize spread of the virus. The study team will inform you of any associated requirements. Despite efforts, there is still the risk that you may have or become infected with SARS-COV-2 and infect others.

If you contract the virus, you may not experience any symptoms. Because this is a novel virus there may be symptoms that we do not know about. The most frequently experienced symptoms are cough, fever, shortness of breath, fatigue, and body aches. These symptoms range from mild to severe illness; the latter may lead to pneumonia and death. Symptoms typically appear 2-14 days after exposure to the virus.

There are certain high risk groups that are more at risk for severe illness including those with chronic kidney disease, COPD (chronic obstructive pulmonary disease that includes conditions such as asthma and emphysema), weakened immune systems, organ transplant recipients, obesity, serious heart conditions, sickle cell disease, and type 2 diabetes.

Some children and adults who have been exposed to the virus develop Multisystem Inflammatory Syndrome (MIS), a condition where different body parts and organs can become inflamed. MIS can be serious and may lead to death. Symptoms may include, but are not limited to fever, chest/abdominal pain, bloodshot eyes, diarrhea, vomiting, neck pain, rash, and fatigue.

For the most up to date list of all possible COVID-19 and MIS symptoms, please refer to the CDC website: https://www.cdc.gov/coronavirus/2019-nCoV/index.html or contact your primary care physician. Not everyone experiences the same symptoms. Contact your primary care physician if you are experiencing symptoms that are concerning to you. Call 911 if you are experiencing trouble breathing, pain or pressure in your chest or abdomen, new confusion, sleeping changes, or pale, gray, or bluish skin, lips, or nail beds.

Please inform the study team if you have any of these symptoms. Please inform the study team if you develop any of these symptoms or have a positive COVID-19 test within 2-14 days of an in person visit with the study team. If you are an individual that is part of a high-risk group as defined by the CDC, please inform the study team.

If you feel as though guidelines are not being followed during your research visits, please talk with the study staff, submit an anonymous complaint through Ethics Point by calling 215-726-6759, or reach out to the Penn IRB at 215-898-2614. Please discuss with your study team, ask all questions you may have.

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07/1/2021 TO: 06/30/2022